



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/548,403

07/27/2006

Marie Bendix Hansen

036179-0108

7935

22428 7590 06/22/2010

FOLEY AND LARDNER LLP

SUITE 500

3000 K STREET NW

WASHINGTON, DC 20007

EXAMINER

KIM, ALEXANDER D

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

06/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/548,403</p>	<p>Applicant(s) HANSEN ET AL.</p>	
	<p>Examiner ALEXANDER D. KIM</p>	<p>Art Unit 1656</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-13 and 15-17.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/David J. Steadman/
Primary Examiner, Art Unit 1656

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's amendment after final rejection, filed on 06/11/2010, is acknowledged and has been entered.

Previous objection to claim 1 is withdrawn by virtue of Applicants' claim amendment.

Applicants' arguments in the amendment filed on 06/11/2010 have been fully considered. However, applicant's arguments are not found persuasive to overcome the outstanding rejection(s) as set forth in the Final Office action mailed on 4/12/2010 for the reasons of record stated therein. Applicants argue the Examiner exaggerated the reach of the teaching of Lihme et al., which discloses "it is possible to apply EBA without the limitation in size and flow rate normally associated with packed-bed column"; and argue Lihme et al. teach neither "at least 40°C" nor "a flow rate of 1500 cm/hour" (see page 5, Remarks filed on 6/11/2010). However, applicant appears to directly contradict this statement by acknowledging that Lihme et al. has run the EBA at elevated temperature of 50°C in Example 11 (see page 6, line 9, Remarks filed on 6/11/2010); and use of 1500 cm/hour flow rate in Example 9 (see page 6, line 21, Remarks filed on 6/11/2010).

Applicants also argue that Lihme et al. discloses mixed results achieved with increased temperature and discourage the use of high flow rate because of decreased yield (see page 6, Remarks filed on 6/11/2010); thus, Lihme et al. would have directed the skilled artisan away from using high temperature and high flow rate. According to MPEP 2144.05.II, "[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical". In the art of protein purification, it was well-known at the time of the invention that yield is dependent upon many factors, including temperature and flow rate. Specifically, in an industrial setting, the overall yield may be decreased in terms of % recovery, however, it would have been obvious to one ordinarily skilled in the art to increase flow rate and temperature to adapt the purification process as necessary to obtain optimal market adaptation as taught by Lihme et al. (see middle of page 6, final office action mailed on 4/12/2010). Thus, the temperature range and flow rate range recited in instant claims are not novel and unobvious for one skilled in the art, particularly as there is no evidence of record that such temperature and flow rate are critical.

Applicants argue how IgG in combination with the teachings Lihme et al. could render the claimed EBA chromatography obvious (see top of page 7, Remarks filed on 6/11/2010). However, given the combined overall teachings and what was known at the time of instant invention with respect to EBA technology by one ordinarily skilled in the art in view of Lihme et al., the instant claims reciting certain temperature, flow rate and/or size (i.e., molecular weight) of the molecule of interest are neither novel or unobvious features.

Applicants further argue that the Olander reference "flow rate of about 812 cm/hour" is far less than at least 1500 cm/hour and is silent as to temperature and the instant invention is distinguished over Olander's teachings or in combination with the teachings of Lihme et al. who discourages the use of high temperature and flow rate (see middle of page 7, Remarks filed on 6/11/2010). It is noted that Olander reference is a supporting reference to the teachings of Lihme et al. under 35 U. S. C. 103(a) which does not have to teach all the limitations as long as the combined teachings support "a reasonable expectation of success" and motivation to do so as noted in the previous Office actions, wherein the motivation to modify or apply the teachings of Lihme et al. is to develop or adapt an EBA purification procedure with "more efficient and cost effective production method" (see page 11, line 10, final office action mailed on 4/12/2010) and "a cost-effective industrial-scale method for production of components from whey and milk" in combination of the teachings of Olander et al. (see page 11, line 10, final office action mailed on 4/12/2010).

At least for the reasons of record and the reasons set forth above, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention.